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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/964,161	09/26/2001	John Clifford Head	CELL-0145	9582

7590 05/05/2004

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EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/964,161

Applicant(s)

HEAD ET AL.

Examiner

Tamthom N. Truong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,4-6,8-11 and 14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-6,8-11 and 14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Applicant's amendment of 02-20-04 has been fully considered. Applicant's argument on the rejection of "Scope of Enablement" has been found persuasive. Therefore, said rejection is withdrawn herein. However, an update search yields a pertinent reference, which raises the following new ground of rejection. Also, some new issues of 112/2<sup>nd</sup> have been noted.

With claims 2, 3, 7, 12, and 13 cancelled, only claims 1, 4-6, 8-11, and 14 are pending.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1, 4-6, 8-11, and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 8 recite the phrase "*optionally substituted*" renders said claims and all dependent claims indefinite because there are no specific moieties intended for substituents. In the absence of specific moieties intended to effectuate modification by "substitution" or attachment to the chemical core claimed, the term "substituted" renders the claims in which it appears indefinite in all occurrences wherein applicant fails to articulate by chemical name, structural formula or sufficiently distinct functional language, the particular moieties applicant

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regards as those which will facilitate substitution, requisite to identifying the composition of matter claimed.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

2. Claims 1, 4, 6, and 14 are rejected under 35 U.S.C. 102(a) as being anticipated by **Willson et. al.** (WO 97/31907). On page 13, Willson et. al. lists several compounds, one of which anticipates the following claims (see the compound on line 17 of page 13):

- a. Claim 1: the compound wherein:
  - i.  $R^a$  and  $R^b$ , each is hydrogen;
  - ii.  $L^1$  is O, and  $s = 1$ ;
  - iii.  $Alk^1$  is heteroaliphatic chain (e.g., methyl-amino-ethyl-);  $r = 1$ ;
  - iv.  $R^1$  is  $C_8$ -heteroaromatic group (e.g., benzoxazol-2-yl);
  - v.  $Alk^2$  is an alkylene;  $m = 1$ ;
  - vi.  $R^2$  and  $R^3$ , each is hydrogen;
  - vii. R is  $-COOH$ ;

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- viii. Het is a nine-membered fused-ring heteroaromatic group (e.g., 4-oxo-4H-chromene).
- b. Claim 4: the compound of claim 1 wherein R is -CO<sub>2</sub>H.
- c. Claim 6: the compound of claim 1 wherein each of R<sup>2</sup> and R<sup>3</sup> is a hydrogen atom.
- d. Claim 14: a pharmaceutical composition comprising a compound of claim 1.

Thus, the teaching of Willson et. al. reads on all limitations of the above claims.


***References cited on PTO-892***

3. Besides the above reference, the three US patents cited on PTO-892 disclose relevant compounds. However, their publications do not antedate the effective filing date of this application. Thus, they are not competent prior arts.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-F (~10 am ~ 6:30 pm).

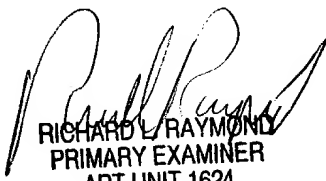
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached at 571-272-0674. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting SPE of 1624, at 571-272-0661.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

  
T. Truong

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April 29, 2004

  
RICHARD L. RAYMOND  
PRIMARY EXAMINER  
ART UNIT 1624